

**Navajo Nation Human Research Review Board  
Institutional Review Board Meeting Agenda**

DATE: May 15, 2018,

TIME: 9:00 AM

PLACE: NDOH Conference Room,  
Window Rock, AZ

**MEMBERS:**

Dr. Mark C. Bauer, Ph.D. - Scientific Education  
Beverly Becenti-Pigman, **Chairperson** – Community  
Dr. David Begay, Ph.D. - Scientific Education  
Rebecca Izzo-Manymules, MPH, (C) *Ph.D.* – Education  
Vida Khow, MHSA, BSN – Health Policy  
Ursula Knoki-Wilson, MSN, MPH - Nursing  
Wallace McGilbert - Community  
Dr. Raymond Reid, MD, MPH - Medicine  
Dr. Calvin White, Ph.D. - Scientific Education

**OLD BUSINESS:**

- I. Meeting Call to Order:
- II. Roll Call:
  - Invocation:
  - Introductions:
- III. Review and Approval of Agenda:
- IV. Review and Approval of January 16, 2018 Meeting Minutes:

**NEW BUSINESS:**

- V. Quarterly Reports:
- VI. Serious Adverse Events (SAEs):
- VII. New Presentations:
- VIII. Returning Presentations:
- IX. Noon Hour Discussions:
- X. Manuscripts / Abstracts Review:
- XI. Announcements / Adjournment:

**Navajo Nation Human Research Review Board  
IRB 5/15/2018 Meeting Agenda**

**ADVERSE EVENT**

1. NNR-02.110 PI: Knowler, William MD  
**Diabetes Prevention Program Outcomes Study (DPPOS)**
2. NNR-17.282 PI: Hammitt, Laura M.D.  
**A Study to Evaluate the Efficacy of Maternal Immunization with RSV F vaccine in Preventing RSV Lower Respiratory Tract Infection in Young Infants (RSV-M-302)**
3. NNR-16.264 PI: Reid, Raymond M.D.  
**Preventing Early Childhood Obesity, Part I: Family Spirit Nurture, 3-9 Months.**

**NEW PRESENTATION(S)**

1. NNR-18.304T PI: Howley, Caitlin MS  
**Indigenous Math Circles Community (IMACC) Evaluation**  
Reason on New Title  
Description: Request Review and Approval of New Study
2. NNR-18.305T PI: Bigknife Antonio, Molly  
**Navajo Weavers: Following Threads of Relationships**  
Reason on New Title  
Description: Request Review and Approval of new Study

**RETURNING PRESENTATION(S)**

1. NNR-01.085 PI: Reid, Raymond M.D.  
**Effect of Pneumococcal Conjugate Vaccine on Nasopharyngeal Colonization among Adult Household Contacts of Vaccinated**  
Reason on Quarterly Review  
Description: Request Review and Acceptance of Quarterly Report covering January 1 - March 31, 2018 period
2. NNR-02.105 PI: Reid, Raymond M.D.  
**Epidemiology Study of Pneumonia among Navajo and White Mountain Apache Adults**  
Reason on Quarterly Review  
Description: Request Review and Acceptance of Quarterly Report covering January 1 - March 31, 2018 period
3. NNR-02.110 PI: Knowler, William MD  
**Diabetes Prevention Program Outcomes Study (DPPOS)**  
Reason on Quarterly Review  
Description: Request Review and Acceptance of Quarterly Report covering January 1, 2018 - March 31, 2018 period
4. NNR-02.111 PI: Reid, Raymond M.D.  
**Effects of Maternal Influenza Vaccination on Respiratory Disease among Infants**  
Reason on Quarterly Review  
Description: Request Review and Acceptance of Quarterly Report covering January 1 - March 31, 2018 period

5. NNR-04.151 PI: Santosham, Mathuram MD

**A Phase 3 Study of MEDI-524 (Numax®), an Enhanced Potency Humanized Respiratory Syncytial Virus (RSV) Monoclonal Antibody, for the Prevention of RSV Disease Among Navajo and White Mountain Apache Infants in the Southwestern United**

**Reason on** Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering January 1 - March 31, 2018 period

6. NNR-05.174 PI: Reid, Raymond M.D.

**In-home Prevention of Substance Abuse Risk in Navajo Teen Families**

**Reason on** Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering January 1 - March 31, 2018 period

7. NNR-06.195 PI: Deaton, James

**National Indian Education Study 2007**

**Reason on** Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering January 16 - April 14, 2018 period

8. NNR-07.216 PI: Reid, Raymond M.D.

**Rapid-response investigation of pediatric cases of invasive Haemophilus influenzae in Navajo American Children**

**Reason on** Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering January 1 - March 31, 2018 period

9. NNR-09.255 PI: Reid, Raymond M.D.

**Pilot Study of the Association between Acute Gastroenteritis and Water Quality, Availability, and Handling Practices on the Navajo Nation**

**Reason on** Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering January 1 - March 31, 2018 period

10. NNR-09.259 PI: Santosham, Mathuram MD

**Menu for Life - Assessing Food Security Risk among At-Risk Southwestern Native Americans**

**Reason on** Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering January 1 - March 31, 2018 period

11. NNR-11.150 PI: Shin, Sonya MD

**Evaluating the Navajo Community Outreach and Patient Empowerment (COPE) Program**

**Reason on** Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering November 22, 2017 - March 20, 2018 period

12. NNR-11.319 PI: Patten, Christi A. PhD

**Family Cancer Literacy to Promote Mammography Screening among Navajo Women**

**Reason on** Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering November 23, 2017 - February 22, 2018 period

13. NNR-11.324 PI: Bauer, Mark C. Ph.D

**Cross-Site Evaluation of the Dine College HIV Prevention Demonstration Project for the Navajo Nation**

**Reason on** Quarterly Review

Description: Request Review and Acceptance of two Quarterly Reports covering 1) September 20, 2017 - December 20, 2017, 2) December 20, 2017 - March 20, 2018 periods

14. NNR-11.332 PI: Speakman, Kristen MA. MPH

**Evaluation of an Edible School Garden Program; Evaluation of the Feast for the Future Community Visioning Program.**

**Reason on** Quarterly Review;

Description: Request Review and Acceptance of Quarterly Report covering January 1 - March 31, 2018 period

15. NNR-11.346 PI: Reid, Raymond M.D.

**Together on Diabetes Study: Evaluation of a pilot Diabetes Prevention and Management Program for American Indian Youth.**

**Reason on** Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering January 1 - March 31, 2018 period

16. NNR-15.212 PI: Solomon, Mark G.

**2015 Safety Belt Use Estimates for the Indian Nations.**

**Reason on** Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering January 1, 2018 - March 31, 2018 period

17. NNR-16.238 PI: Hammitt, Laura M.D.

**Active Bacterial Surveillance for Staphylococcus aureus on the Navajo and White Mountain Apache Reservations.**

**Reason on** Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering January 1 - March 31, 2018 period

18. NNR-16.239 PI: Chee, Donald B.A.

**Integrated HIV/AIDS & Substance Abuse Prevention Project for the Navajo Nation**

**Reason on** Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering November 16, 2017 - February 16, 2019 period

19. NNR-16.251 PI: Frank, Daniel MS

**Investigating Culturally-Contextualized Making with the Navajo Nation**

**Reason on** Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering January 20 - April 19, 2018 period. Included a workshop sing in sheet.

20. NNR-16.258 PI: Swaim, Randall C. Ph.D.

**Substance use among American Indian Youth attending schools on or near Reservation**

**Reason on** Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering January 1, 2018 - March 31, 2018 period

21. NNR-16.260 PI: Eddie, Regina S. Ph.D., MS, RN

**A Socio-Ecological Analysis of Childhood Obesity and School Nutrition Policies and Practices in Select Elementary and Middle Schools on the Navajo Reservation.**

**Reason on** Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering February - April 2018 period

22. NNR-17.274 PI: Jumbo-Fitch, Rosanna M.A. B.S

**Intergrating Din'e Culture and Language to Transform Construction Management Curriculum**

**Reason on** Quarterly Review

Description: Request Review and Acceptance of Quarterly Reports 1) July 1, 2017 - October 31, 2017; 2) January 1, 2018 - March 31, 2018 periods

23. NNR-17.281 PI: Garrison, Nanibaa' Ph.D.

**Perspectives on Genetic Research in the Navajo Nation**

**Reason on** Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering January 1 - March 23, 2018 period

24. NNR-17.283 PI: Russell, Maureen Ph.D., OTR/L

**Sleep Interventions for Caregivers and their Young Children in Part C Programs**

**Reason on** Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering December 20, 2017 - March 19, 2018 period

25. NNR-17.284 PI: Yazzie, Delvin MPH

**Navajo Nation Healthy Dine' Act: An Implementation Study**

**Reason on** Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering February 2018 - April 2018 period

26. NNR-16.254 PI: Reid, Raymond M.D.

**Evaluation of NativeVision Year Round Program**

**Reason on** Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering January 1 - March 31, 2018 period

27. NNR-16.255 PI: Radovanovic, Sonja D Ph.D., M.A.

**First Things First Navajo Regional Partnership Council**

**Reason on** Final Report

Description: Request Acceptance and Approval of Final Report covering September 20, 2016 - May 15, 2018 period

28. NNR-02.094 PI: Knowler, William MD

**Action for Health in Diabetes Look AHEAD**

**Reason on** Amendment

Description: Request Acceptance and Approval of Amendment to Protocol Revised Consent Form V19 to cover Cognitive Testing for next two years.

**Reason on** Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering January 1, 2018 - April 6, 2018 period

**Reason on** Amendment

Description: Request Acceptance and Approval of Consent Forms 1) Main Consent Form, 2) Verbal Consent Form.

**Reason on** Continuation Request

Description: Request Acceptance and Approval of Continuation Request covering August 19, 2018 - August 19, 2019 period

29. NNR-11.152 PI: Leischow, Scott J. PhD ***TABLED Use Documents from April 17, 2018 Meeting Packet***

**Networks among Tribal Organizations for Clean Air Policies**

**Reason on** Annual Report

Description: Request Acceptance and Approval of Annual Report covering April 18, 2017- April 17, 2018 period

**Reason on** Addendum

Description: Request Acceptance and Approval of Addendum of Mayor IRB approval letter to continuation of protocol.

**Reason on** Continuation Request

Description: Request Acceptance and Approval of Continuation Request covering April 18, 2018 - April 18, 2019 period

30. NNR-11.342 PI: O'Connell, Joan M. Ph.D.

**Comparative Effectiveness of Healthcare Delivery Systems for American Indian and Alaska Native using Enhanced Data**

**Reason on** Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering February 16 - May 15, 2018 period

**Reason on** Annual Report

Description: Request Acceptance and Approval of Annual Report covering May 15, 2017 - May 15, 2018 period

**Reason on** Amendment

Description: Request Review and Approval of Amendment to Protocol - Purchase and Referred Care Utilization for I.H.S.

**Reason on** Addendum

Description: Request Acceptance and Approval to Protocol of 1) Colorado Multiple IRB Approval, 2) I.H.S. Nation IRB Approval, 3) Two pay Project overview.

**Reason on** Continuation Request

Description: Request Acceptance and Approval of Continuation Request covering MAY 15, 2018 - May 15, 2019 period.

31. NNR-15.208 PI: Pollari, Lynette

**Dine Cultural Sustainability through Settlement Form: "Finding Patterns for New Navajo Neighborhoods:**

**Reason on** Annual Report

Description: Request Acceptance and Approval of Annual Report covering May 19, 2017 - May 19, 2018 period

32. NNR-15.224 PI: Watanabe, Kohei

**Ethnography of Laughter: Laughter of Dine and Creation of Hozo**

**Reason on** Conference Presentation

Description: Request Review and Acceptance of Request Conference Presentation at 52nd Annual Conference of the Japanese Society of Cultural Anthropology on June 2, 2018 at Hirosaki University, Hirosaki Aomori, Japan.

**Reason on** Annual Report

Description: Request Acceptance and Approval of Annual Report covering February 16, 2017 - February 16, 2018 period.

33. NNR-16.242 PI: Begay, Shawna L. MFA

**Developing a Navajo Educational Media Guide: A Community Perspective.**

**Reason on** Annual Report

Description: Request Acceptance and Approval of Annual Report covering April 19, 2016 - April 19, 2017 period

**Reason on** Continuation Request

Description: Request Acceptance and Approval of Continuation Request covering April 19, 2017 - April 19, 2018

34. NNR-16.245 PI: Gittelsohn, Joel Ph.D.

**Engaging Tribal Policy Makers to Sustain Improvements to the Food and Physical Activity in American Indian Communities (OPREVENT2)**

**Reason on** Amendment

Description: Request Acceptance and Approval of Amendment to revise Survey questionnaires.

35. NNR-16.257 PI: Lombard, Kevin A. PhD

**Engaging Family and School in Navajo Gardening for Health**

**Reason on** Modification

Description: Request Acceptance and Approval of Modification to Protocol of Outreach and Intervention of Project.

- Reason on** Continuation Request;  
**Description:** Request Acceptance and Approval of Continuation Request covering September 19, 2017 - September 18, 2019 period  
 36. NNR-16.264 PI: Reid, Raymond M.D.
- Preventing Early Childhood Obesity, Part I: Family Spirit Nurture, 3-9 Months.**  
**Reason on** Amendment  
**Description:** Request Acceptance and Approval of Amendments of new recruitments: 1) Navajo Posters, 2) Video Script, 3) JHU IRB approval
- Reason on** Quarterly Review  
**Description:** Request Review and Acceptance of Quarterly Reports covering: January 1 - March 31, 2018 part I, II.  
 37. NAR-96.013 PI: Santosham, Mathuram MD
- Epidemiology and Immunology of Respiratory Syncytial Virus Infections in Navajo and Apache Infants.**  
**Reason on** Quarterly Review  
**Description:** Request Review and Acceptance of Quarterly Report covering January 1 - March 31, 2018 period
- Reason on** Continuation Request  
**Description:** Request Acceptance and Approval of Continuation Request covering June 19, 2018 - June 19, 2019 period  
 38. NNR-01.081 PI: Bauer, Mark C. Ph.D
- Making a Difference: The Role of Family Support in Navajo Diabetics' Selfcare**  
**Reason on** Quarterly Review  
**Description:** Request Review and Acceptance of Quarterly Report covering December 27, 2017 - March 27, 2018 period
- Reason on** Annual Report  
**Description:** Request Acceptance and Approval of Annual Report covering March 20, 2017 - March 20, 2018 period  
 39. NNR-11.349 PI: Bauer, Mark C. Ph.D
- Navajo Gardening, Nutrition, and Community Wellness**  
**Reason on** Quarterly Review;  
**Description:** Request Review and Acceptance of Quarterly Report covering January 17 - April 17, 2018 period.
- Reason on** Annual Report  
**Description:** Request Acceptance and Approval of Annual Report covering April 17, 2017 - April 17, 2018 period  
 40. NNR-16.244 PI: Bauer, Mark C. Ph.D
- Identifying and Reinforcing Positive Behaviors among Dine' College Students**  
**Reason on** Annual Report  
**Description:** Request Acceptance and Approval of Annual Report covering April 17, 2017 - April 17, 2018 period
- Reason on** Amendment  
**Description:** Request Acceptance and Approval of Two Campaign Posters for Project
- Reason on** Quarterly Review  
**Description:** Request Review and Acceptance of Quarterly Report covering October 20, 2017 - January 19, 2018 period
- Last page and end of Agenda*